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| APPLICATION NO.  | FILING DATE          | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|----------------------|----------------------|----------------------|------------------|
| 10/528,179   | 03/17/2005           | Yuji Yoshimura       | 268119US0PCT         | 6504             |
| 22850 7590 03/16/2007<br>OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET |                      |                      | EXAMINER             |                  |
|  |                      |                      | SEAMAN, D MARGARET M |                  |
| ALEXANDRIA, VA 22314   |                      | ART UNIT             | PAPER NUMBER         |                  |
|  |                      |                      | 1625                 |                  |
|  |                      |                      |                      |                  |
| SHORTENED STATUTORY  | Y PERIOD OF RESPONSE | NOTIFICATION DATE    | DELIVERY MODE        |                  |
| 3 MONTHS   |                      | 03/16/2007           | ELECTRONIC           |                  |

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/16/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com oblonpat@oblon.com jgardner@oblon.com

|   | Application No.  | Applicant(s)  |  |  |  |
|---|--|---|--|--|--|
|   | 10/528,179   | YOSHIMURA ET AL.  |  |  |  |
| Office Action Summary   | Examiner   | Art Unit  |  |  |  |
|   | D. Margaret Seaman   | 1625  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirr will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | 1.  nely filed  the mailing date of this communication.  D (35 U.S.C. § 133). |  |  |  |
| Status  |  |   |  |  |  |
| <ul> <li>1) ⊠ Responsive to communication(s) filed on 27 Dec</li> <li>2a) ☐ This action is FINAL.</li> <li>2b) ☒ This</li> <li>3) ☐ Since this application is in condition for allower closed in accordance with the practice under E</li> </ul>  | action is non-final.<br>nce except for formal matters, pro   |   |  |  |  |
| Disposition of Claims   |  |   |  |  |  |
| 4) ⊠ Claim(s) 1-8 is/are pending in the application.  4a) Of the above claim(s) 8 is/are withdrawn from  5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) 1-7 is/are rejected.  7) □ Claim(s) is/are objected to.  8) □ Claim(s) are subject to restriction and/or  |  |   |  |  |  |
| Application Papers  |  |   |  |  |  |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the example Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex  | epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj  | e 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).                           |  |  |  |
| Priority under 35 U.S.C. § 119  |  |   |  |  |  |
| <ul> <li>12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a)  All b)  Some * c) None of:</li> <li>1.  Certified copies of the priority documents have been received.</li> <li>2.  Certified copies of the priority documents have been received in Application No</li> <li>3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |  |   |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 4) Interview Summary Paper No(s)/Mail Da   | nte   |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application 6) Other:   |  |   |  |  |  |

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## **DETAILED ACTION**

1. This application was filed 3/17/2005 and is a 371 of PCT/JP03/11643 (9/11/2003) which claims priority to JP 2002-275015 (9/11/2002). Claim 8 remains withdrawn from consideration. Claims 1-7 are before the Examiner. RCE papers were filed 12/27/2006.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda (US Patent 5939552), Nagamatsu (1999), Chen (US Patent6835838) and Onishi (US Patent #6946557) in view of Gebauer(CA 129:197349, 1998), Davey (CA 117:229369), Iwuagwu (CA 105:178553), Peng (CA 99:110835), Wang (CA 97:203288), Hara (CA 93:185599) and Thiem (CA 89:175853).

As previously stated, Ikeda teaches simulated moving bed chromatographic process (see abstract) for the resolution of the instant compound (col 4 line 40) using a mixed solvent (column 6 lines 46-47) and silica gel of a certain particle size (col 6 lines 10-30). Nagamatsu teaches the same process (see abstract,, pages 55, 56, 58). Onishi

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teaches the same process (see column 3 line 15, col4 line 10, col 6 lines 33-35, col 7 line 30, col 8 line 14). Chen teaches the same process using HPLC: Chiralpak AD; eluent, hexane/I-PrOH see col 17 line45). These references fully teach the instant invention with the exception of the silica gel as packing material being uncoated.

Gebauer (CA 129:197349, 1998), Davey (CA 117:229369), Iwuagwu (CA 105:178553), Peng (CA 99:110835), Wang (CA 97:203288), Hara (CA 93:185599) and Thiem (CA 89:175853) all teach the use of uncoated silica gel being used to separate compounds, including isomers and epimers.

Optical resolution of a racemic mixture separates one specific compound (one epimer) from a mixture of compounds (epimers). The art teaches silica gel as the packing material and than uncoated silica gel is used frequently by the ordinary artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 730am-4pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. Margaret Seaman Primary Examiner Art Unit 1625

dms